

## **Remarks**

### **A. *Specification***

The Office Action noted the use of trademarks in the paragraph beginning at page 9, line 28, and ending at page 10, line 9. This paragraph has been amended to remove the trademark symbols from the terms TEGADERM and OPSITE FLEXIGRID.

### **B. *Information Disclosure Statement***

Applicants appreciate the Examiner's recommendations and comments regarding the information disclosure statement (IDS). Applicants do not interpret the comments to suggest that Applicants are "cloaking . . . clearly relevant references"—any such suggestion would be false. Applicants appreciate the Examiner's recognition that Applicants have no duty to comment on the materiality of any reference, the Examiner's consideration of the references cited in the IDS, and the notation of such consideration on the IDS.

### **C. *Status of the Claims***

Claims 1-11 were pending prior to the Office Action mailed April 9, 2010. The Advisory Action noted that the Applicant's prior submission did not support the portion of the specification relied upon to support the claim amendments. To the extent there is any doubt, examples of portions of the specification that support the claim amendments are now set forth below.

Independent claim 1 is amended to recite "at least one discrete opening extending through a top surface of the cover such that the at least one discrete opening is configured to communicate negative pressure directly to an undermined portion of the wound." Support for the amendment to claim 1 can be found throughout the specification and drawings, as originally filed; such as, for example, at Fig. 5; p. 4, ll. 14-17; p. 9, ll. 4-6 .

Independent claim 8 is amended to recite “wherein a majority of the generally continuous planar bottom surface is directly engaged with the top surface of the wound contactable layer such that the cover cooperates with the channels extending along the top surface of the wound contactable layer to define a plurality of passageways connecting each hole with the port” and “the cover configured to substantially prevent communication of negative pressure through the bottom surface of the cover.” Support for the amendment to claim 8 can be found throughout the specification and claims, as originally filed; such as, for example, at Figs. 2 and 3 which clearly depict a majority of the generally continuous planar bottom surface of the cover directly engaged with the top surface of the wound contactable layer.

Independent claim 9 is amended to remove the phrase “and which are uncovered at the top surface,” and to recite “the second plurality of discrete holes and the plurality of peripheral access channels configured to communicate negative pressure directly to an undermined portion of the wound.” Support for the amendment to claim 9 can be found throughout the specification and drawings, as originally filed; such as, for example, at Fig. 5; p. 4, ll. 14-17; p. 9, ll. 4-6 .

No new matter is added by these amendments. Claims 1-11 remain pending.

***D. Claims 1-11 Are Definite***

Claims 1-11 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**1. “uncovered at the top surface”**

The Office states that independent claims 1 and 9 are “unclear/inconsistent” because the “the undermined portion of the wound covers the opening at the top surface.” Office Action at 4. Applicants respectfully disagree. The member is not claimed in the wound (the undermined

portion of the wound does not even arguably cover the opening when not in a wound). Nevertheless, claims 1 and 9 have been amended to expedite prosecution. Claim 1 now recites “at least one discrete opening extending through a top surface of the cover such that the at least one discrete opening is configured to communicate negative pressure directly to an undermined portion of the wound.” The phrase “uncovered at the top surface” has been removed from claim 9, which now recites “the second plurality of discrete holes and the plurality of peripheral access channels configured to communicate negative pressure directly to an undermined portion of the wound.” Applicants believe these amendments fully address this portion of the rejection.

### **2. “substantially all of the generally planar bottom surface”**

The Office further states that “the description of ‘substantially all of’ the generally planar bottom surface directly engaging the top surface of the wound contactable layer on lines 11-12 but ‘cooperating with the channels extending along the top surface of the wound contactable layer to define a plurality of passageways’ on lines 12-13 is unclear/inconsistent.” Action at 5. Applicants respectfully disagree. Nevertheless, claim 8 has been amended to recite wherein a majority of the generally continuous planar bottom surface is directly engaged with the top surface of the wound contactable layer such that the cover cooperates with the channels extending along the top surface of the wound contactable layer to define a plurality of passageways connecting each hole with the port.” Applicants believe these amendments fully address this portion of the rejection.

### **3. “generally non-porous”**

The Office further states that, with respect to claims 1 and 9, “the description of the cover as being ‘generally non-porous’ . . . but having ‘at least one discrete opening extending through a top surface of the cover’ is unclear/inconsistent.” Applicants respectfully disagree and traverse.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:"

- (A)The content of the particular application disclosure;
- (B)The teachings of the prior art; and
- (C)The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

MPEP §2173.02. Under each of the considerations *required by the MPEP*, the Office's interpretation of "generally non-porous" is unreasonable.

First, the contents of the present application clearly support the definiteness of "generally non-porous." The background section discusses the *porous* materials of the prior art:

- at page 1, lines 15-16: "a *porous* packing may be provided under the cover to fill the space in which the vacuum is formed (emphasis added);"
- at page 1, lines 23-28: "As shown, for example, in U.S. Patent No. 5,645,081 . . . Fig. 1 of the '081 patent discloses an *open cell polyester foam* section covering the wound (emphasis added);"

recap action, the Office suggests that Applicant's arguments are "narrower than the prior art" because page 1, lines 23-28 of the present specification discuss open cell foam rather than all foams. The Office is mistaken, and clearly ignores Applicant's reference to page 1, lines 15-16 of the specification, which discusses the use of porous packing in the prior art.

The specification and originally filed claims make clear that "generally non-porous" is distinct from the porous foams and gauze of the prior art:

- at page 3, lines 4-12: "The member may further include a plurality of discrete holes . . . . The member may be formed from a *generally non-porous* material (emphasis added);"
- at page 5, lines 15-27: "As shown in Fig. 4, *access openings* include both access channels 62 and *access holes* 64 . . . Referring now to Fig. 4, member 19, layer 20, cover 22, and connector 23 are each made of a medical grade silicone or other type of pliable elastomer. . . . It is within the scope of this disclosure, however, to

include a member made of any type of thin, flexible material *that is non-porous and non-foam-like* (emphasis added);” and

- at originally filed claims 1 and 6: “a plurality of discrete holes . . . at least one discrete opening” (claim 1), and “wherein the member is formed from a generally non-porous material” (claim 6).

In the Advisory Action, the Office notes that the specification discusses “nonporous and non-foam-like” material. The office is correct that the claim language does not recite this phrase verbatim. But the Office misses the point. There is absolutely no requirement that the claims recited verbatim language from the specification. And to the extent that there is any doubt, originally filed claims 6 and 12 recited a “generally non-porous material.” As the office is aware, original claims constitute their own description. *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980). The specification and original claims use “generally non-porous” to describe the member material—even though it includes one or more holes and/or openings. Thus, the Office’s interpretation plainly ignores the specification that *must* guide claim interpretation.

Applicants also note that the Office improperly divorces the phrase “generally non-porous” from the context of the specification and claims. Rather than interpreting this phrase consistently with and in light of the context of its use in the specification and claims (including originally filed claims), the Office improperly attempts to define this phrase in the isolation of dictionary definitions dated years after the application was filed. The Office’s attempt to interpret this phrase without reference to the specification is plainly improper.

In the Advisory Action, the Office also references the Examiner’s “similarly presented positions in the Office Action 6-22-07” with regard to “nonporous.” In that Office Action, the Office took the position that “nonporous” precluded any holes or openings. As such, the currently recited “generally non-porous” should fully address the Office’s prior concerns. The use

of "generally" is plainly different from the claim language addressed in the referenced 2007 Office Action, and highlights the unreasonableness of the Office's current rejection.

Second, the prior art uses "porous" to describe foam and gauze. *See, e.g.*, Present Application at p. 1, ll. 10-28 (discussing porous packing of prior art and listing U.S. Pat. No. 5,648,081 as an example with "polyester foam"); Risk '807 at col. 10, ll. 35-37 ("porous packing 618 . . . is typically a gauze material"). This interpretation is consistent with relevant technical definitions of "porous." For example, the MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS, FIFTH EDITION defines "porous" as "1. **Filled** with pores. 2. Capable of **absorbing** liquids." Appendix 1 at 1549 (emphasis added). Foam is porous; gauze is porous—both are "filled with pores." Neither foam nor gauze can be described as "generally non-porous." Further, a person of ordinary skill in the art would understand that a "generally non-porous" cover is generally not "capable of absorbing liquids." *See, e.g.*, Appendix 1 at 7 (defining "absorb" as "[t]o take up a substance in bulk").

Third, a person of ordinary skill in the art would have no difficulty discerning the meaning of the claim. The Office must consider "the totality of all the limitations of the claim and their interaction with each other." *In re Larson*, No. 01-1092 (May 9, 2001) (citing *Radio Steel & Mfg. Co. v. MTD Prods., Inc.*, 731 F.2d 840, 845, 221 USPQ 657, 661 (Fed. Cir. 1984)). The totality of the claims supports the definiteness of "generally non-porous." For example, "generally non-porous" clearly does not require *entirely* non-porous. Further, claim 1 recites a "at least one **discrete** opening extending through a top surface of the cover" (emphasis added). The MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS, FIFTH EDITION defines "discrete" as "1. Composed of **separate and distinct** parts. 2. Having an **individually distinct** identity." Appendix 1 at 589 (emphasis added). A person of ordinary skill in the art would thus

understand “at least one *discrete* opening” to be different than one of the ill-defined and innumerable pores of foam or gauze. By way of illustration, a block of foam is porous, but a block of steel is generally non-porous. Even if one or more *discrete* holes are drilled in the block of steel, a person of ordinary skill in the art would still understand the block of steel to be “generally non-porous.” This is all section 112, second paragraph, requires.

Independent claims 1, 8, and 9, and therefore dependent claims 2-7 and 10-11 which depend therefrom, are definite. Applicants therefore respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112.

***D. Claim Language Interpretation***

Applicant believes the foregoing remarks with respect to the indefiniteness rejections fully address the Office’s concerns regarding the interpretation of “generally non-porous.”

With respect to “generally continuous planar bottom surface,” the Office states:

Due to the lack of clarity discussed supra, claim 8, lines 11-12 will be interpreted to require a generally continuous bottom surface with no projections extending directly therefrom which extends between an outer perimeter of the cover and some portion thereof is directly engaged with the top surface of the wound layer.

The Office’s interpretation is again unreasonable. The phrase “generally continuous planar bottom surface” is clear on its face; there is no need to re-write it as the Office has done.

***E. Claims 1-11 Are Novel***

Claims 1-11 were rejected under 35 U.S.C. § 102(e) as anticipated by Risk Jr. et al. (6,755,807, hereinafter referred to as Risk ‘807), and “thereby, by incorporation,” Lockwood et al. (6,685,681, hereinafter referred to as Lockwood ‘681). Office Action at 6. Applicants respectfully disagree and traverse.

## 1. Independent claims 1 and 9

As the Office is aware, anticipation requires a single reference that disclose *all elements of a claim*. Neither Risk '807 nor Lockwood '681 discloses all elements of independent claims 1, 8, and 9, nor of dependent claims 2-7 and 10-11. Even if the packing 618 of Risk '807 (see FIG. 9) is equated to the cover recited in any of claims 1, 8, and 9, Risk '807 simply does not disclose or suggest that the packing 618 could have the claimed characteristics. “[S]ide 612 of bandage member 604 faces wound 300 , and side 610 faces a *porous* packing 618 . . . Packing 618 is typically a *gauze material*.” Col. 10, ll. 33-37 (emphasis added). But independent claims 1 and 9, as amended, recite “a *generally non-porous* cover coupled to the wound contactable layer.” Risk '807 explicitly discloses a *porous* packing, and thus does not and cannot disclose a *generally non-porous* packing, as recited in independent claims 1 and 9. Common sense dictates that Risk’s “porous packing” (e.g., gauze) *cannot* be *generally non-porous*.

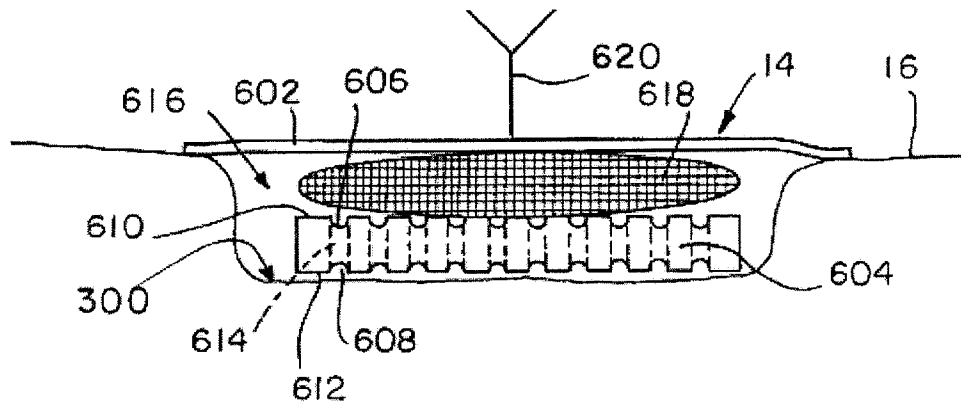
## 2. Independent claim 8

At the outset, the rejection of claim 8 does not even address the claimed feature: “outer portions of the channels extending between an outer edge of the cover and an outer edge of the wound contactable layer defining a plurality of peripheral access channels configured to communicate negative pressure to an undermined portion of the wound.” The rejection is therefore insufficient as a matter of law because it fails to address every feature of the claim.

Independent claim 8 recites “a cover coupled to the wound contactable layer and having a *generally continuous planar* bottom surface” (emphasis added). FIG. 9 of Risk '807 shows that packing 618 does not have a “generally continuous planar bottom surface”—as required by the claim. The Office’s interpretation of this phrase is unreasonable. All five words must be given effect: (1) *generally*; (2) *continuous*; (3) *planar*; (4) *bottom*; (5) *surface*.



For example, the dictionary cited by the Office, Merriam-Webster Online, defines “continuous” as “marked by *uninterrupted* extension in space, time, or sequence.” Appendix 2 (emphasis added). The porous packing 618 (e.g., “typically a gauze material”) of Risk ‘807 explicitly does not have a “generally continuous planar bottom surface.” Instead, a porous material like gauze is, by its very nature, discontinuous.



**Relevant Portion of FIG. 9 of Risk ‘807**

Additionally, claim 8 has been amended to recite “the cover configured to substantially prevent communication of negative pressure through the bottom surface of the cover.” Regardless of the claim language interpretation, *porous* packing 18 does not substantially prevent communication of negative pressure through a bottom surface.

Further, neither reference discloses “outer portions of the channels extending between an outer edge of the cover and an outer edge of the wound contactable layer defining a plurality of peripheral access channels configured to communicate negative pressure to an undermined portion of the wound.”

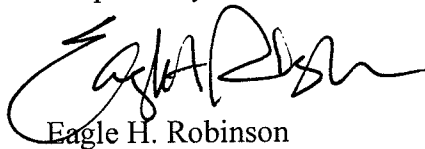
Neither Risk ‘807 nor Lockwood ‘681 discloses every element of the present claims. Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

### Conclusion

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application.

Should the Examiner desire to sustain any of the rejections discussed in relation to this Response, the courtesy of a telephonic conference between the Examiner, the Examiner's supervisor, and the undersigned attorney at 512-536-3083 is respectfully requested.

Respectfully submitted,



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